

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
12 September 2002 (12.09.2002)

PCT

(10) International Publication Number
WO 02/070037 A2

(51) International Patent Classification⁷: A61M

Andrews Circle, Gilroy, CA 95020 (US). ZHANG, Cynthia; 19361 Bellwood, Saratoga, CA 95070 (US).

(21) International Application Number: PCT/US02/06701

(22) International Filing Date: 4 March 2002 (04.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/273,490 4 March 2001 (04.03.2001) US
60/299,842 19 June 2001 (19.06.2001) US

(71) Applicant: STERLING MEDIVATIONS, INC.
[US/US]; 6025A Unity Drive, Norcross, GA 30071 (US).

(72) Inventors: DOUGLAS, Joel, S.; 25285 La Loma Drive, Los Altos, CA 94022 (US). HUGO, Robert, L.; 1923 St.

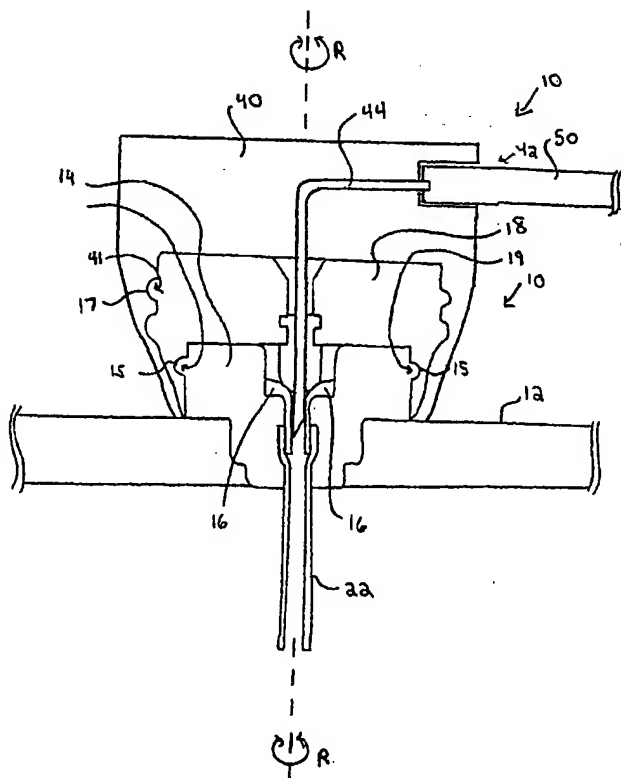
(74) Agents: HECKADON, David, R. et al.; Burns, Doane, Swecker & Mathis, LLP., P.O. Box 1404, Alexandria, VA 22314-1404 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,

[Continued on next page]

(54) Title: INFUSION HUB ASSEMBLY AND FLUID LINE DISCONNECT SYSTEM



(57) Abstract: An infusion hub assembly, comprising: a hub received in a hole in a wing, the hub having a bore passing therethrough, with an upper portion of the circular hub having an attachment surface thereon; an infusion cannula extending downwardly away from the wing, the infusion cannula being in fluid communication with the bore passing through the hub; a cover having a bore passing therethrough and having an inner attachment surface adapted to mate with the attachment surface on the upper portion of the hub; and a septum positioned in alignment with the bore passing through the cover. An infusion connector set comprising: a first connector; a septum received in the first connector; a second connector; a septum received in the second connector; and a flanged needle which penetrates both the septums in the first and second connectors when the first and second connectors are connected together.

WO 02/070037 A2



GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *without international search report and to be republished
upon receipt of that report*

-1-

INFUSION HUB ASSEMBLY AND FLUID LINE DISCONNECT SYSTEM

Related Application

The present application claims the benefit of priority under 35 U.S.C.
5 Section 119 to U.S. provisional patent application Ser. Nos. 60/273,490 filed
March 4, 2001 and 60/299,842 filed June 19, 2001.

Summary of the Invention:

[0001] In various embodiments, the present invention provides an infusion hub
assembly, comprising: a wing having a hole passing therethrough; a hub received
10 in the hole in the wing, the hub having a bore passing therethrough, with an upper
portion of the circular hub having an attachment surface thereon; an infusion
cannula extending downwardly away from the wing, the infusion cannula being in
fluid communication with the bore passing through the hub; a cover having a bore
passing therethrough with an inner attachment surface adapted to mate with the
15 attachment surface on the upper portion of the hub; and a septum positioned in
alignment with the bore passing through the cover.

[0002] In various embodiments, the upper portion of the hub is circular and has an
attachment surface extending circumferentially therearound. In various
embodiments, this attachment surface comprises a lip extending circumferentially
20 therearound.

[0003] The present infusion hub assembly comprises a cover having a bore
through which an insertion needle is positioned when initially positioning the wing

-2-

of the assembly on a patient's skin with the infusion cannula extending subcutaneously. In various embodiments, the cover holds a septum therein to advantageously seal the pathway into the patient (when the insertion needle is not piercing therethrough).

- 5 [0004] In various embodiments, the cover is dimensioned to be snap-fit over the infusion hub. In various embodiments, the cover has a central bore through which the insertion needle passes when the assembly is positioned subcutaneously.

- 10 [0005] Thereafter, the novel rotatable infusion housing is attached onto the top of the cover. In various embodiments, the rotatable housing has an attachment surface adapted to mate with an outer attachment surface on the upper portion of the cover. Thus, in various embodiments, the rotatable housing is also dimensioned to be snap-fit over the cover, which is in turn snap-fit over the infusion hub.

- 15 [0006] In various aspects, the attachment surface on both the cover and the rotatable housing comprises a recess extending circumferentially therearound. These recesses mate with lips extending from an upper portion of the infusion hub and the cover, respectively. In various aspects, the infusion hub and the rotatable housing are circular such that the rotatable housing can turn freely, while still providing continuous infusion of medication (or other desired fluid substances)
20 subcutaneously into the patient.

[0007] In various embodiments, the rotatable housing comprises a curved needle passing at least partially through a radial bore in the rotatable housing, wherein a first end of the curved needle is positioned to extend downwardly into the bores in the cover and the hub when the rotatable housing is attached to the cover.

-3-

Additionally, an infusion tube is received into the radial bore of the rotatable housing in fluid communication with the curved needle.

[0008] Advantages of having a rotatable infusion housing which can turn freely, while still providing continuous infusion subcutaneously into the patient include:

- 5 (i) avoiding kinks in the infusion tube, and (ii) avoiding having to tape the infusion housing to the patient, thus (iii) permitting the patient to position an infusion pump (which feeds fluid into the infusion tube) at different locations on the patient's body.

10 [0009] In another aspect of the invention, the present invention provides an infusion connector set comprising: a proximal connector; a septum received in the proximal connector; a distal connector; a septum received in the distal connector; and a flanged needle which penetrates both the septums in the proximal and distal connectors when the proximal and distal connectors are connected together.

15 [0010] It is to be understood, however, that reference made herein to a "proximal" and "distal" connector is only exemplary. Thus, the flanged needle may instead move to various positions within the distal connector rather than within the proximal connector. Accordingly, the present invention refers to a "first" and a "second" connector. In various embodiments, the "first" connector is the "proximal" connector and the "second" connector is the "distal" connector. In
20 alternate embodiments, the connectors are reversed such that the "first" connector is the "distal" connector and the "second" connector is the "proximal" connector.

[0011] In various embodiments, the flanged needle is slidably movable within a slot in the distal connector. In various aspects, the flanged needle may be moved to

-4-

a position at which the needle does not penetrate the proximal septum in the proximal connector, yet is still held within the proximal connector.

[0012] Thus, when the proximal and distal connectors are fastened together, the needle provides a fluid path therethrough. When the distal connectors is
5 uncoupled from the proximal connector, the septum in the distal connector will seal (since the flanged needle is held within the proximal connector, and thus is no longer in contact with the septum in the distal connector).

[0013] In various embodiments, the flange of the flanged needle protrudes through the slot in the distal connector such that an operator may grab onto the flange and
10 move the flanged needle along in the slot in the distal connector. Thus, the flanged needle may conveniently be moved to a position in which the needle no longer penetrates the septum in the proximal connector. Thus, the septum in the proximal connector will seal itself, preventing contamination or exposure to the substance being delivered through the infusion tubing.

[0014] An advantage of having the proximal and distal connector easily
15 disconnectable from one another (with their respective septums sealing the fluid path through both connectors) is that it facilitates switching between different infusion lines.

[0015] A further advantage of providing the distal connector with its own septum
20 is that a patient can manually disconnect the proximal and distal connectors and then inject a syringe (containing an alternate medication or substance) through the septum in the distal connector, and into the patient.

-5-

5 [0016] In various embodiments, the infusion connector set further comprises a retainer mounted at the distal end of the proximal connector. In various embodiments, this retainer closes the distal end of the slot in the proximal connector, such that movement of the flanged needle is retained to back and forth movement within the proximal connector.

10 [0017] In various embodiments, the proximal and distal connectors are dimensioned such that one connector may be inserted into the other, and then rotated into an interlocked position. This may be achieved by providing one of the connectors with at least one tab extending therefrom, and the other of the connectors with at least one recess therein. The at least one recess is dimensioned to receive the at least one tab therein when the proximal and distal connectors are connected together. In various embodiments, the connector comprising the at least one tab is the proximal connector, and the connector comprising the at least one slot is the distal connector.

15 [0018] Still other features and advantages of the present invention will become apparent to those skilled in the art from a reading of the following detailed description of embodiments constructed in accordance therewith, taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

[0019] Fig. 1 is a sectional side elevation view of an infusion hub assembly according to the present invention.

5 [0020] Fig. 2 is a sectional side elevation view similar to Fig. 1, but with an insertion needle passing therethrough.

[0021] Fig. 3 is a sectional side elevation view similar to Figs. 1 and 2, but with the insertion needle removed, and replaced by a rotatable infusion housing.

[0022] Fig. 4 is a perspective view of the assembled infusion hub assembly.

[0023] Fig. 5 is a side elevation view of the assembled infusion hub assembly.

10 [0024] Fig. 6 is an exploded perspective view of the present infusion hub assembly, showing alternate positioning of the insertion needle passing through the cover and of the rotatable infusion housing fit over the cover.

[0025] Fig. 7 is a perspective view of an infusion connector set according to the present invention.

15 [0026] Fig. 8 is a perspective view similar to Fig. 7, showing the proximal and distal connector disconnected from one another.

[0027] Fig. 9 is a view similar to Fig. 8, but with the flanged needle moved such that it does not penetrate the proximal septum.

-7-

[0028] Fig. 10 is an exploded perspective view of the proximal connector assembly.

[0029] Fig. 11 is an exploded perspective view of the distal connector assembly.

[0030] Fig. 12 is a schematic sectional view corresponding to Fig. 7.

5 (Corresponding to a view taken along line 12-12 in Fig. 13).

[0031] Fig. 13 is a side elevation view corresponding to Fig. 12 (showing the slot in which the flange supporting the flanged needle moves).

[0032] Fig 14 is a schematic sectional view of the proximal connector of the system of Fig. 12, after the distal connector has been uncoupled and removed and
10 the flanged needle has been moved in the slot such that it does not penetrate the septum in the proximal connector. (Corresponding to a view taken along line 14-14 in Fig. 15).

[0033] Fig. 15 is a side elevation view corresponding to Fig. 14.

Detailed Description of the Drawings

15 [0034] Figs. 1 to 6 illustrate an infusion hub assembly according to the present invention. Figs. 7 to 15 illustrate an infusion connector set according to the present invention.

[0035] Referring first to Figs. 1 to 6, an infusion hub assembly 10 is provided. A large wing or patch 12 having a hole 13 passing therethrough is provided. Wing
20 12 is positioned on the surface of a patient's skin. In various embodiments, the underside of wing 12 has an adhesive surface, securing it to a patient's skin. In

-8-

alternate embodiments, the wing 12 is instead taped directly onto the patient's skin.

[0036] As shown in Fig. 1, assembly 10 comprises wing 12, hub 14 and cover 18. In various aspects, all, or at least the upper portion of hub 14 is circular. Hub 14 is received into a circular shaped hole 13 in wing 12. In various embodiments, hole 13 is stepped in diameter, and circular hub 14 also has a stepped diameter such that hub 14 fits into hole 13, as shown. Circular hub 14 has a central bore passing vertically therethrough. A needle guide 16 is positioned within this bore through circular hub 14 as also shown. Needle guide 16 may be funnel-shaped, and may be made of metal.

[0037] In various aspects, an upper portion of circular hub 14 has an attachment surface onto which cover 18 can be snap fit. For example, various aspects, circular hub 14 has a lip 15 extending at least partially circumferentially therearound. In various embodiments, cover 18 has an interior groove 19 extending at least partially circumferentially therearound. In various embodiments, as well, cover 18 is made of a flexible material such that it can be easily snap-fit over the upper portion of circular hub 14.

[0038] As can also be seen, a septum 20 is also provided. Septum 20 may be held by cover 18 (such that when cover 18 is removed from hub 14, septum 20 is also removed). As can also be seen, septum 20 may be positioned such that it is received within needle guide 16 when cover 18 is positioned over infusion housing 14. Septum 20 may be made from a plug of self-sealing elastomeric material.

[0039] A infusion cannula 22 extends downwardly from wing 12. Thus, infusion cannula 22 is positioned subcutaneously when wing 12 rests on the patient's skin. Infusion cannula 22 is thus used for subcutaneously infusing medication into the

-9-

patient. In various embodiments, the proximal end of infusion cannula 22 may be positioned to be received within the lower portion of circular hub 14, and may also be received around an end of needle guide 16, as shown, however, the present invention is not so limited. Many other systems for attaching infusion cannula 16
5 such that it extends downwardly from wing 12 are also contemplated within the scope of the present invention.

[0040] Referring next to Fig. 2, a various system for positioning assembly 10 such that infusion cannula 22 is positioned subcutaneously is also provided. Specifically, an insertion needle 30, (which is supported by a handle 32) is inserted
10 through the central bores of protective cover 18 and circular hub 14. Thus, needle 30 passes through septum 20, and extends downwardly, passing out the bottom distal end of infusion cannula 22. When needle 30 is inserted through infusion cannula 22, as shown in Fig. 2, the operator simply applies pressure downwardly onto handle 32 such that wing 12 is pushed down into contact with the patient's
15 skin and infusion cannula 22 is subcutaneously inserted.

[0041] After assembly 10 has been positioned with its wing 12 resting against the patient's skin, and with infusion cannula 22 positioned subcutaneously, (i.e.: as shown in Fig. 2), the operator then simply removes needle 30 by pulling upwardly on handle 32. When needle 30 is initially removed, septum 20 will self-seal,
20 ensuring no contamination enters from the atmosphere through cannula 22 and thus into the subcutaneous pathway under the patient's skin.

[0042] After needle 30 is removed, it is replaced by rotatable infusion housing 40, as follows.

-10-

[0043] As shown in Fig. 3, rotatable housing 40 is then attached over cover 18. Rotatable housing 40 may be made of a flexible material such that it can be snap-fit over cover 18 (similar to how cover 18 fits over hub 14). Specifically, rotatable housing 40 may also have an inner attachment surface such as an interior grooves
5 41 which extend at least partially circumferentially therearound.

[0044] An advantage of interior grooves 41 extending at least partially circumferentially around lip 17 of cover 18 is that housing 40 is therefore rotatable with respect to circular housing 14. Thus, as shown in Figs. 4 and 5, housing 40 may freely be rotated in direction R.

10 [0045] Referring back to Fig. 3, an infusion tube 50 may be used to deliver medication (or any other desired substance) subcutaneously to the patient. Tube 50 may be received into a radially extending bore 42 in housing 40. A curved needle 44 may be attached to the end of tube 50, and is positioned such that its
15 downwardly facing distal end is received directly into needle guide 16 in the bore of circular housing 14. Since the distal end of curved needle 44 points downwardly from the center of rotatable housing 40, and is positioned in the central bores passing through cover 18 and circular housing 14, housing 40 is free to rotate in direction R about its central axis while medication or any other desired substance is infused through tube 50.

20 [0046] Fig. 6 shows an exploded view of the present system in which either: (i) the introducing needle 30 or, (ii) the rotatable housing 40 and infusion tube 50 are attached to cover 18 and pass through septum 20, into circular housing 14. As can also be seen, in various embodiments, an optional removable protective cylinder 23 can be received over infusion cannula 22, to protect the cannula and keep the
25 cannula free of contamination prior to its use.

-11-

[0047] Turning now to Figs. 7 to 15, an infusion connector set is also provided. In various aspects, connector assembly 100 comprises a proximal connector 110 and a distal connector 120. It is to be understood that connector 110 could instead be the distal connector and connector 120 could instead be the proximal connector, according to the user's preferences.) As illustrated herein, assembly 100 is used to provide a detachable coupling link mid-way along infusion tube 50. It is to be understood, however, that while connector assembly 100 (Figs. 7 to 15) may be used in conjunction with the infusion hub assembly 10 (Figs. 1 to 6), it need not be. Rather, each of connector assembly 100 and infusion hub assembly 10 may be used separately. Thus, the tube numbered "50" in Figs. 1 to 6 may, or may not, be the same or different from the tubes numbered "50" in Figs. 7 to 15.

[0048] Fig. 7 shows proximal connector 120 and distal connector 110 coupled together. Fig. 8 shows proximal connector 120 and distal connector 110 uncoupled from one another. As will be explained, the present connector set provides a system in which, when the proximal and distal connectors are fastened together, fluid flows freely through the assembly. When the proximal and distal connectors are no longer fastened or coupled together, the present invention provides a novel self-sealing system which prevents contamination from entering the flow path through either of the proximal or distal connectors. Specifically, as will be explained, a self-sealing septum is positioned in each of the proximal and distal connectors. Also, the proximal connector supports a flanged needle assembly which can be moved such that a septum in the proximal needle self-seals as desired.

[0049] Referring to Fig. 10, proximal connector 110 has a septum housing 111 received therein. A self-sealing septum 112 is held in position by septum housing

-12-

111. A flanged needle assembly comprising a flange 114 and a needle 113 is then received therein. As will be explained, flange 114 can be moved up and down in slots 115 in proximal connector 110 (thereby moving needle 113 to different positions). A retainer 116 is then received over flanged needle assembly 113/114.

5 Retainer 116 prevents flange 114 from escaping from slot 115. Thus, needle 113 remains supported within proximal connector 110 at all times.

[0050] Referring to Fig. 11, distal connector 120 has a septum housing 121 received therein. A self-sealing septum 122 is held in position by septum housing 121.

10 [0051] When assembled together, as shown in Fig. 7 (and as illustrated schematically in Figs. 12 and 13), needle 113 penetrates both of septums 111 and 121, permitting flow through tubes 50.

[0052] When the connectors are disconnected from one another, (i.e.: when distal connector 120 is detached from proximal connector 110) needle 113 (which is held

15 within proximal connector 110) will no longer penetrate distal septum 121 in distal connector 120. Thus, distal septum 121 will self-seal, such that the subcutaneous pathway into the patient (i.e.: the path through distal connector 120, tube 50 and rotatable housing 40 into the patient) will be sealed. However, should a user so desire, a separate syringe injection needle may be inserted through distal septum

20 121 in distal connector 120 such that different or additional medication (or other substances) can be subcutaneously introduced into the patient.

[0053] In accordance with the present invention, a novel system of sealing proximal septum 111 in proximal connector 110 is also provided. Referring to Fig. 9 (and to schematic Figs. 14 and 15), flange 114 is moved distally along slot

-13-

115 such that it carries needle 113 to a position at which it no longer penetrates proximal septum 111.

[0054] In various embodiments, flange 114 protrudes slightly through slots 115 on opposite sides of proximal connector 110, to permit an operator to grasp onto
5 flange 114 and slide it into a position against retainer 116 (such that needle 113 no longer pierces septum 111).

-14-

WHAT IS CLAIMED IS:

1. An infusion hub assembly, comprising:
 - a wing having a hole passing therethrough;
 - a hub received in the hole in the wing, the hub having a bore passing therethrough, with an upper portion of the circular hub having an attachment
5 surface thereon;
 - an infusion cannula extending downwardly away from the wing, the infusion cannula being in fluid communication with the bore passing through the hub;
 - a cover having a bore passing therethrough and having an inner attachment
10 surface adapted to mate with the attachment surface on the upper portion of the hub; and
 - a septum positioned in alignment with the bore passing through the cover.
2. The assembly of Claim 1, wherein the upper portion of the hub is circular.
3. The assembly of Claim 2, wherein the attachment surface on the upper
15 portion of the circular hub comprises a lip extending circumferentially therearound.
4. The assembly of Claim 1, wherein an underside surface of the wing comprises an adhesive layer.
5. The assembly of Claim 1, wherein the hole in the wing is a stepped hole
20 and the hub has a stepped outer dimension which fits into the stepped hole in the wing.

-15-

6. The assembly of Claim 5, wherein both the stepped hole and the hub are circular and the hub has a stepped outer diameter.
7. The assembly of Claim 1, further comprising:
a needle guide received in the bore of the hub.
- 5 8. The assembly of Claim 7, wherein the needle guide is funnel shaped.
9. The assembly of Claim 7, wherein the infusion cannula is attached to the needle guide.
10. The assembly of Claim 1, wherein the upper portion of the cover is circular.
- 10 11. The assembly of Claim 1, wherein the inner attachment surface on the cover comprises a recess extending circumferentially around an internal surface of the cover.
12. The assembly of Claim 1, wherein the cover further comprises an outer attachment surface.
- 15 13. The assembly of Claim 12, wherein the outer attachment surface on the cover comprises a lip extending circumferentially therearound.
14. The assembly of Claim 13, further comprising:
a needle guide received in the bore of the hub, wherein the septum is received into the needle guide when the cover is attached to the hub.

-16-

15. The assembly of Claim 13, further comprising:
a removable insertion needle passing through the bore in the cover, the septum and the infusion cannula, wherein a distal end of the insertion needle extends downwardly out of the distal end of the infusion cannula.
- 5 16. The assembly of Claim 1, further comprising:
a rotatable housing having an attachment surface adapted to mate with the outer attachment surface on the upper portion of the cover.
- 10 17. The assembly of Claim 16, wherein the attachment surface on the rotatable housing comprises a recess extending circumferentially around an internal surface of the rotatable housing.
18. The assembly of Claim 16, wherein the rotatable housing has a radial bore.
- 15 19. The assembly of Claim 18, further comprising:
a curved needle passing at least partially through the radial bore in the rotatable housing, wherein a first end of the curved needle is positioned to extend downwardly into the bores in the cover and hub when the rotatable housing is attached to the cover.

-17-

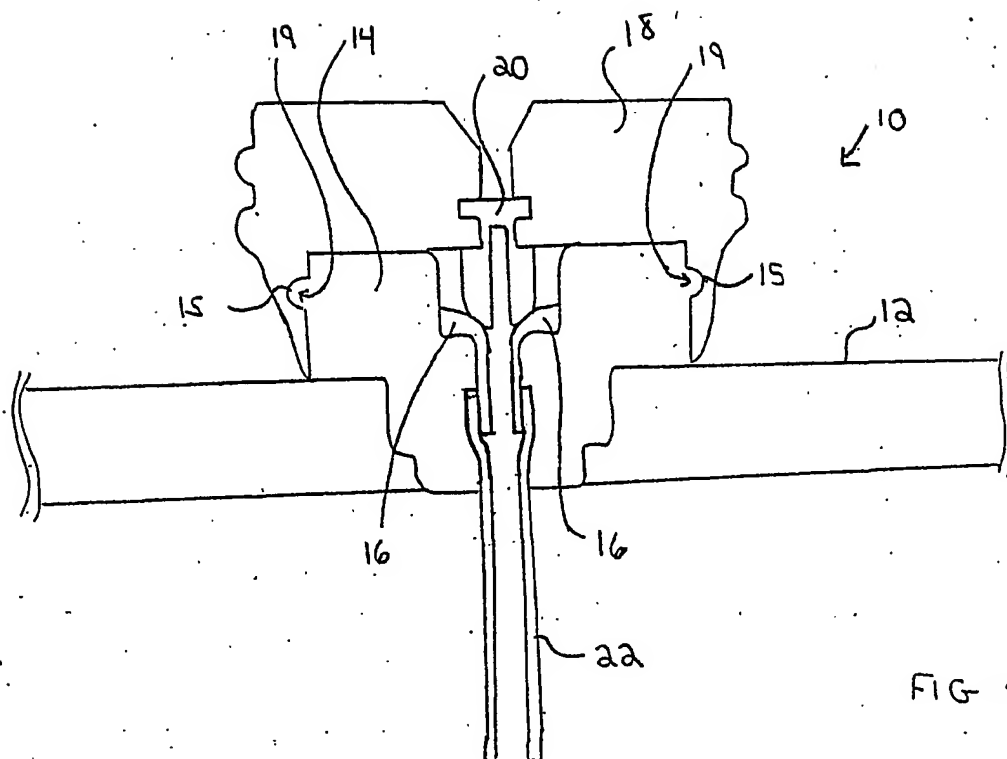
20. The assembly of Claim 19, further comprising:
a tube received into the radial bore of the rotatable housing in fluid communication with the curved needle.
21. The assembly of Claim 20, wherein a second end of the curved needle is received into the tube.
22. An infusion connector set comprising:
a first connector;
a septum received in the first connector;
a second connector;
a septum received in the second connector; and
a flanged needle which penetrates both the septums in the first and second connectors when the first and second connectors are connected together.
23. The infusion connector set of Claim 22, wherein the flanged needle is slidably movable within a slot in the second connector.
24. The infusion connector set of Claim 23, wherein the flange of the flanged needle protrudes through the slot in the second connector such that an operator may grab onto the flange and move the flanged needle along in the slot in the second connector.

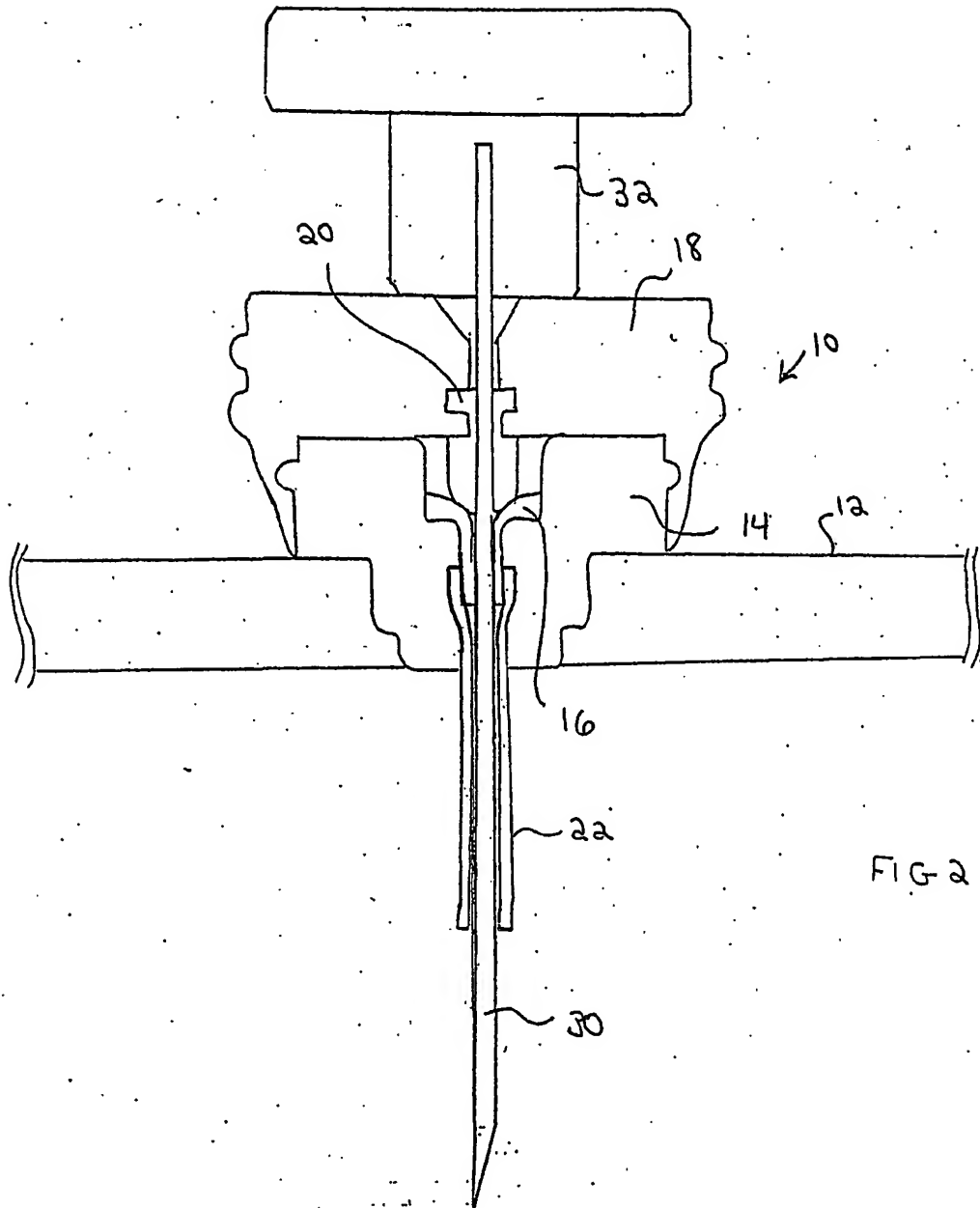
-18-

25. The infusion connector set of Claim 23, further comprising:
a retainer mounted at the distal end of the first connector, the retainer closing the second end of the slot in the first connector, such that the flanged needle is retained within the first connector.
- 5 26. The infusion connector set of Claim 23, wherein the flanged needle may be moved to a position at which the needle does not penetrate the septum in the first connector, yet is still held within the first connector.
27. The infusion connector set of Claim 22, wherein the first and second connectors are dimensioned such that one connector may be inserted into the other,
10 and rotated into an interlocked position.
28. The infusion connector set of Claim 27, wherein one of the connectors comprise at least one tab extending therefrom, and wherein the other connector comprises at least one recess therein, wherein the at least one recess is dimensioned to receive the at least one tab therein when the first and second
15 connectors are connected together.
29. The infusion connector set of Claim 27, wherein the connector comprising the at least one recess has a longitudinal section of the recess and a circumferential section of the recess such that the tab can be inserted into the longitudinal section of the recess and then rotated in the circumferential section of the recess.
- 20 30. The infusion connector set of Claim 22, wherein the first connector is the proximal connector and the second connector is the distal connector.

-19-

31. The infusion connector set of Claim 28, wherein the connector comprising the at least one tab is the proximal connector, and the connector comprising the at least one slot is the distal connector.





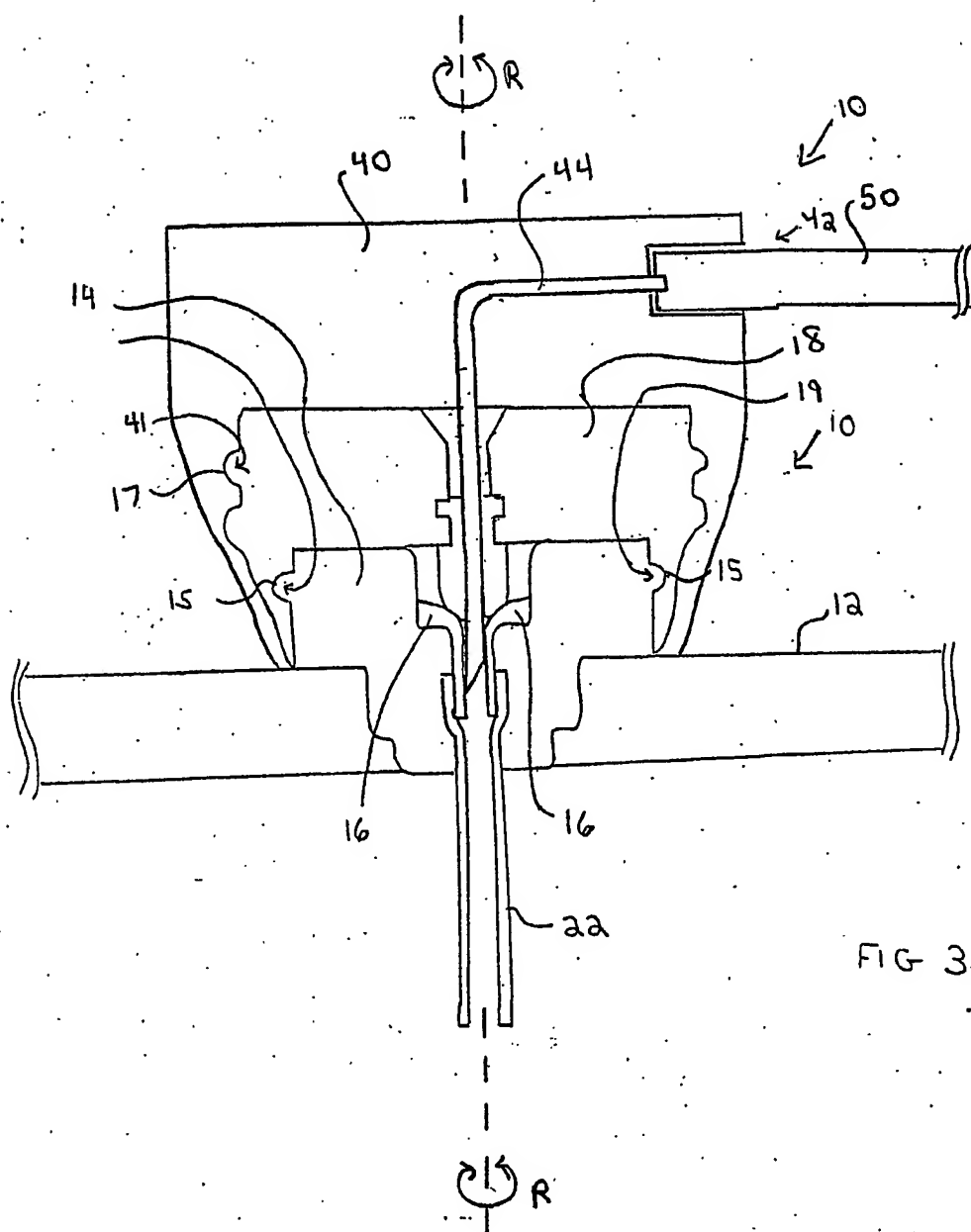


FIG 4

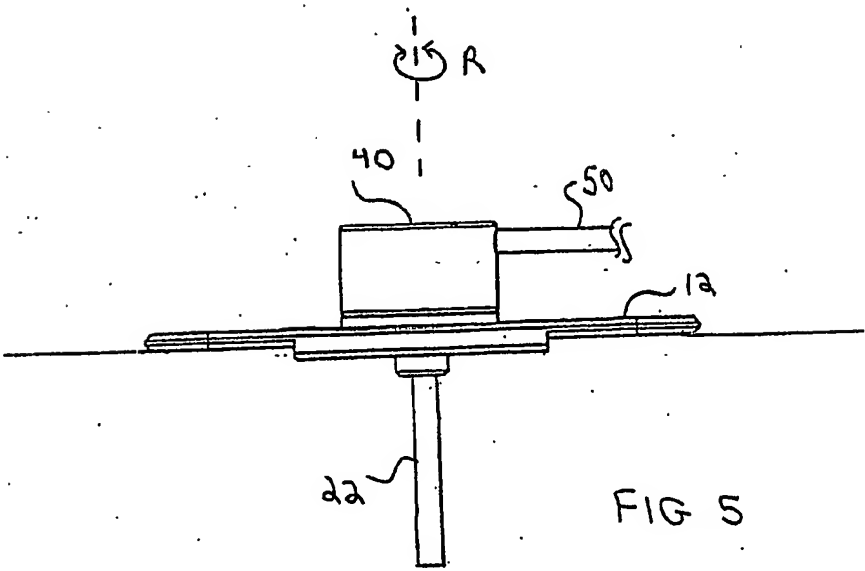
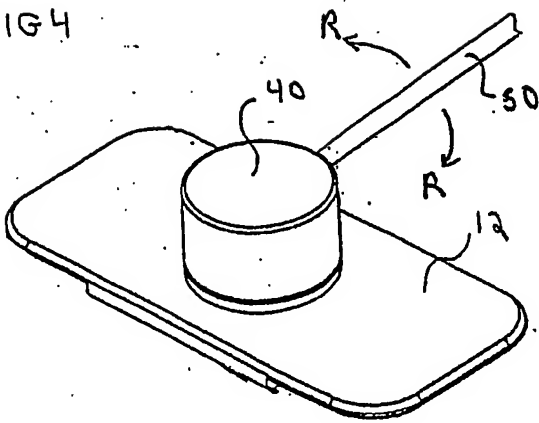
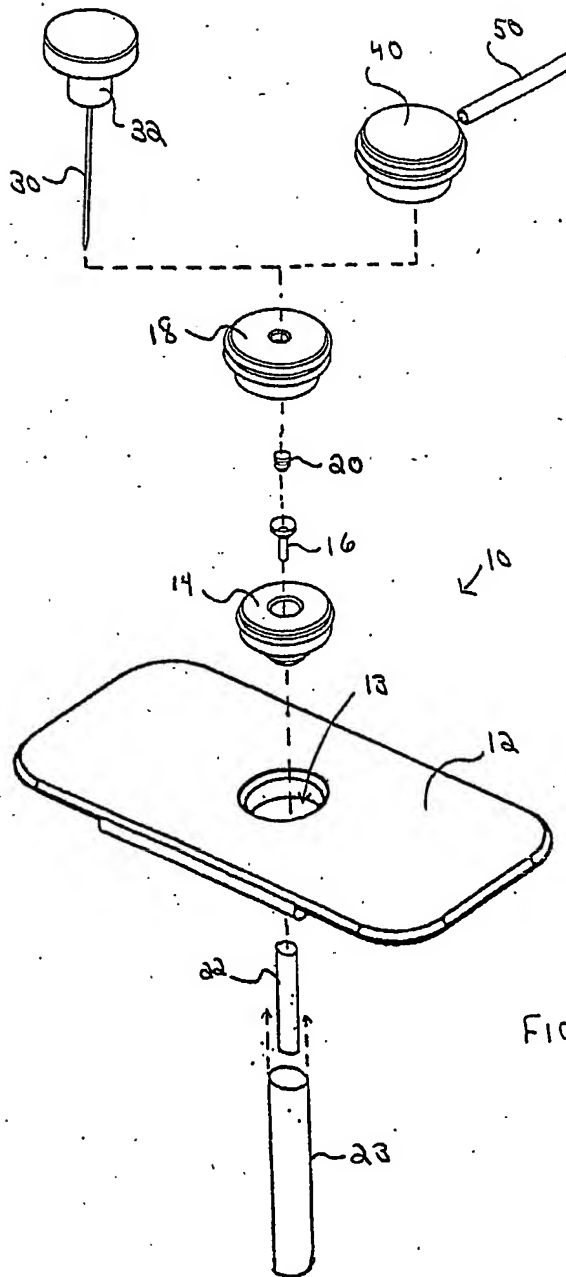


FIG 5



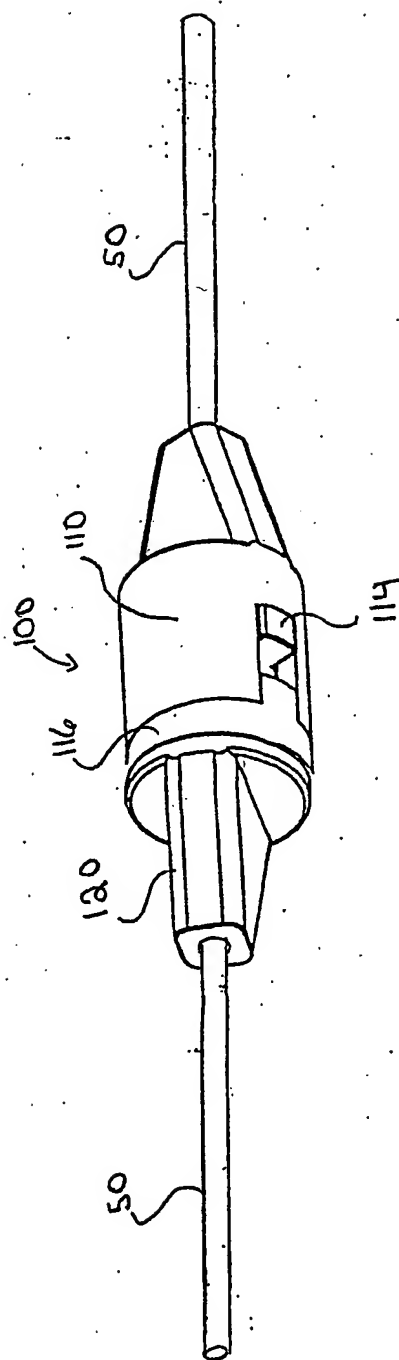


FIG. 7

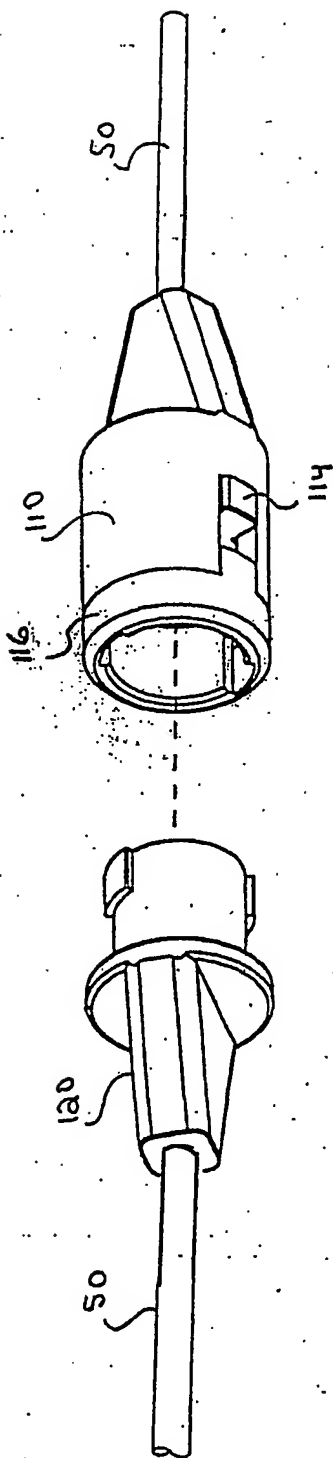


FIG. 8

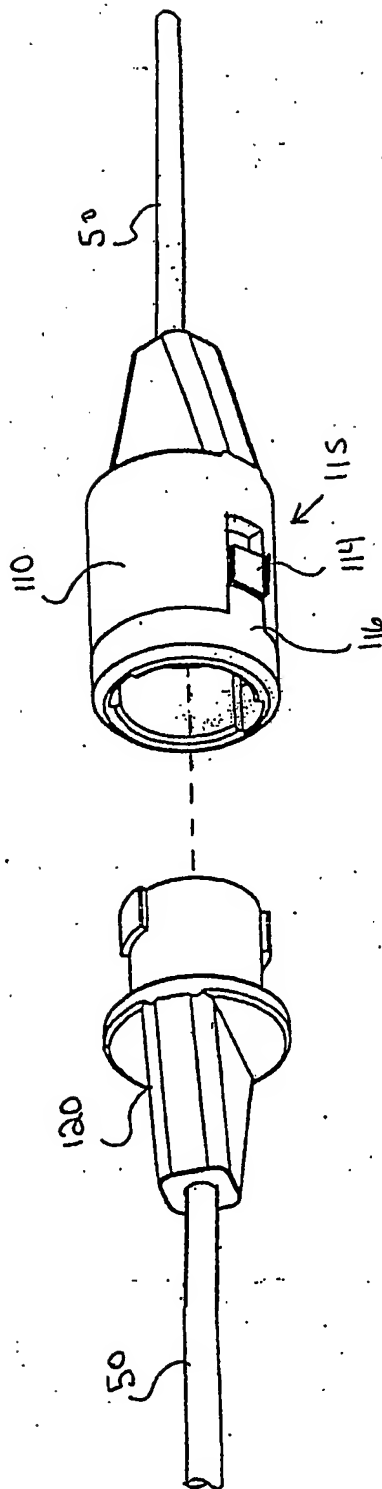


FIG. 9

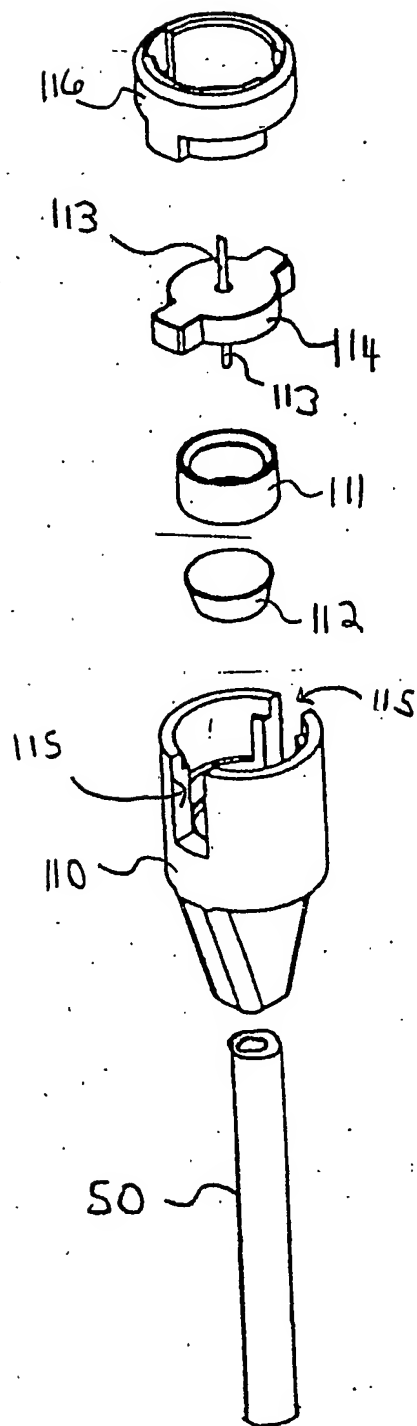


FIG 10

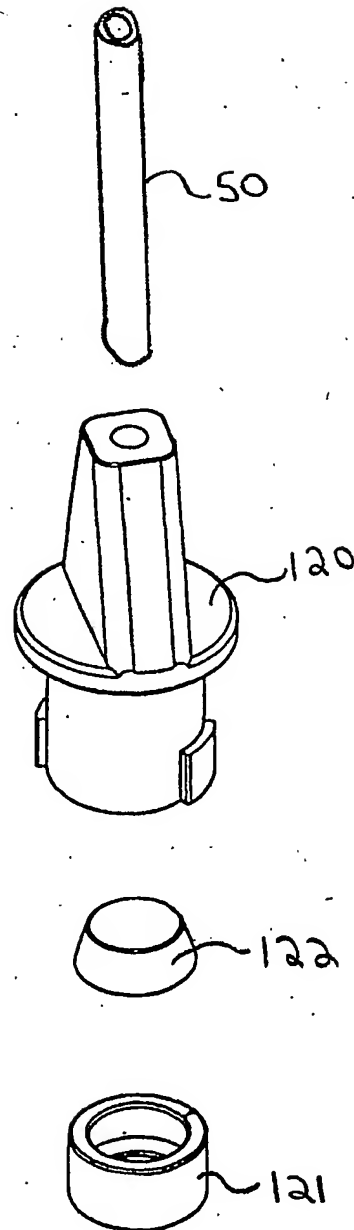


FIG 11

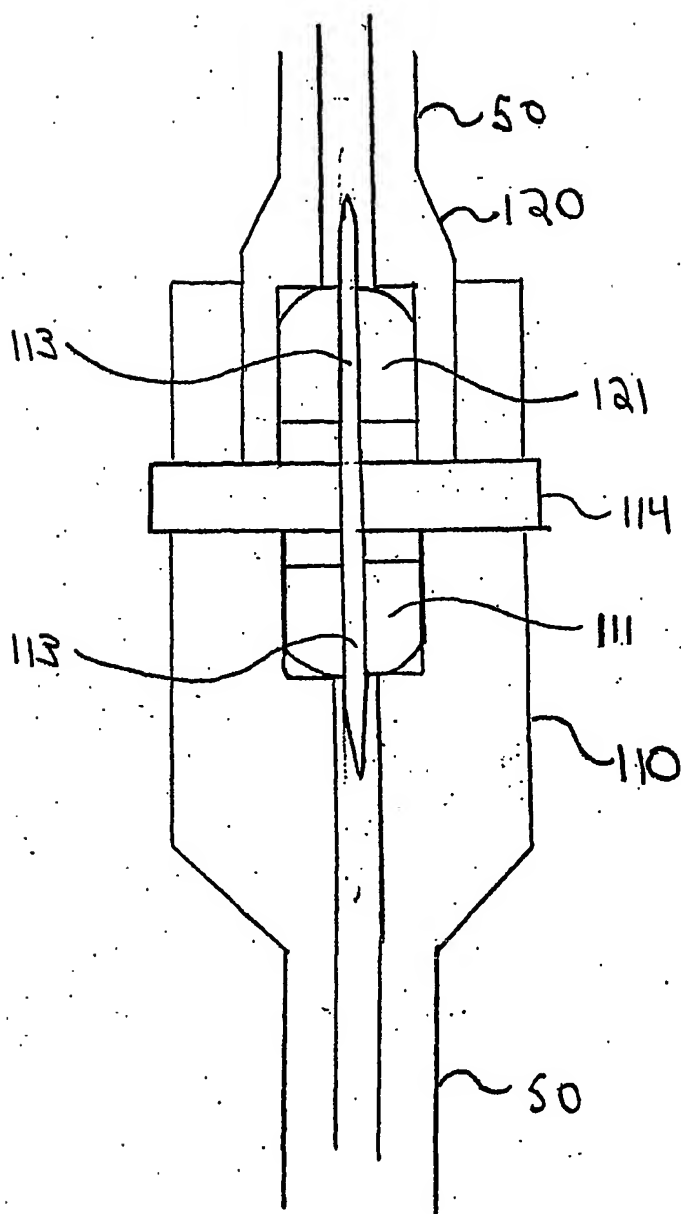
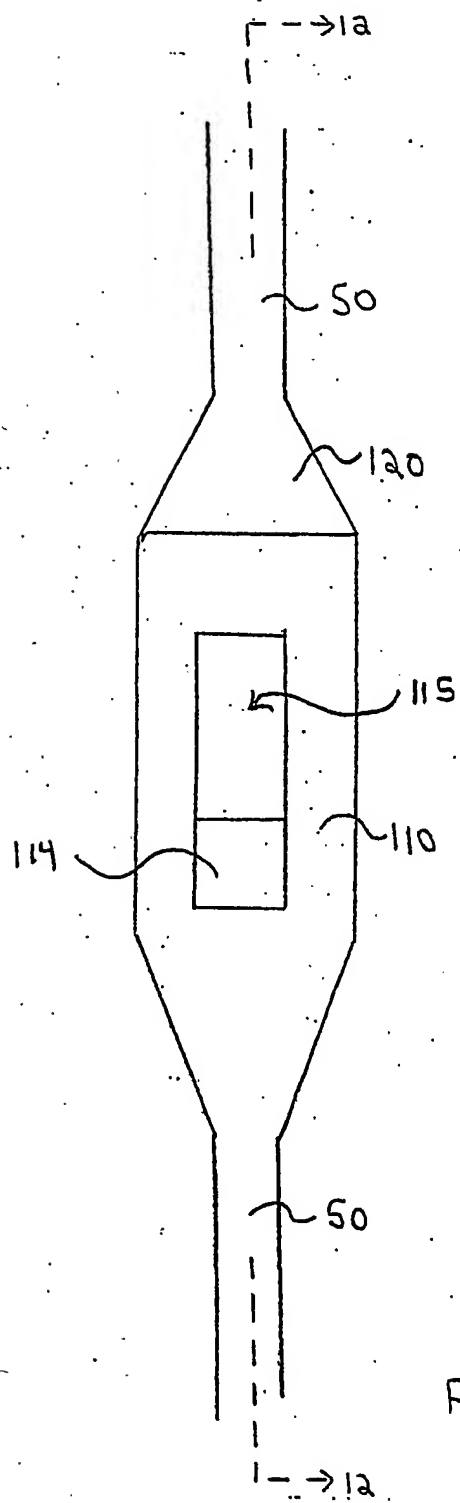


FIG 12



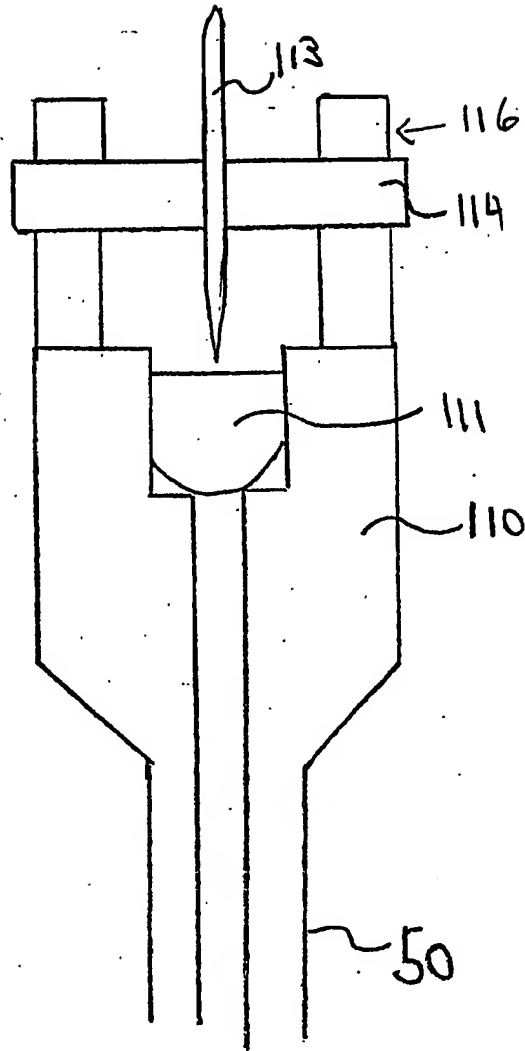


FIG 14

